b) allowing the suspension to settle to yield a supernatant and a sediment comprising high molecular weight hydroxypropylmethylcellulose;

c) discarding the supernatant, and leaving the sediment;

d) resuspending the sediment in a second part of the aqueous solution to form a gel;

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e) filtering the gel through a plurality of successively finer filters to remove harmful particulate and gelatinous matter to form a clean solution; and

f) sterilizing the clean solution.

REMARKS

Claims 1-56 are pending in the present application. By her Office Action dated September 24, 2002, the Examiner rejected claims 1-30 and objected to claims 31-56 as being improperly presented. Subsequent to applicant's receipt of the September 24 Office Action, applicant was granted telephonic interviews with Examiner William Dixon, Jr. The following remarks are responsive to the Examiner's Office Action, and address the issues raised by Examiner Dixon.

In her September 24, 2002, Office Action, Examiner Fay objects to claims 31-56, noting that such claims "must be entirely underlined." Applicant agrees with Examiner Fay, and notes that claims 31-56 were presented in proper form in the applicant's May 9, 2002, Response and Amendment. See pages 12-16 of said Response and Amendment. This issue was also addressed in the applicant's telephonic interview with Examiner Dixon. As evidenced by Examiner Dixon's Interview Summary mailed November 13, 2002, Examiner Dixon indicates that he had consultations with Joe Narcavage and that they agreed "that original claims presented as newly added claims 31+ are not improper and are allowable...."

Applicant respectfully submits, therefore, that claims 31-56 are presently in condition for allowance.

By her Office Action, Examiner Fay also rejected claims 1-30 under 35 USC § 251 as "being broadened in a reissue application filed outside the two year statutory period." Applicant respectfully traverses. This broadening reissue application was filed June 5, 1997, which is within the two year window following issuance of Patent No. 5,422,376 (the '376 patent) on June 6, 1995. When applicant raised this issue during telephonic communications, it was conceded that the broadening reissue application was indeed timely filed, and that the asserted basis for rejection is therefore improper.

In his Interview Summary, Examiner Dixon, "relying primarily on Hester v Stein," has taken the position that claims 1-30 violate the recapture doctrine, and further asserts that "Office/examiner will maintain this position through Appeal." Specifically, Examiner Dixon has taken the position that omission of the "0.5 μm" limitaiton from the issued claims of the '376 patent, in the manner of present claims 1-30 is impermissible. For the reasons stated in its Response and Amendment dated May 9, 2002, which reasons are incorporated herein, applicant respectfully submits that Hester v. Stein is inapposite in the present case, and that claims 1-30 originally filed with the present reissue application in no way violate the recapture doctrine. Applicant continues to maintain that the "0.5 μm" limitation is not critical to patentability and that it was never characterized as such during the prosecution leading to the issuance of the '376 patent.

Nevertheless, in the interest of furthering the prosecution of the present application, applicant has amended the independent claims within claims 1-30 (i.e. claims 1, 13, 25, and 27) to require that the harmful particulate matter and gels be greater than 0.5 μm in diameter. The omission of the 0.5 μm limitation in the originally filed reissue claims appears to have provided the sole basis for Examiner Dixon's position that the recapture doctrine had been violated. By the present amendment, that limitation has been reinstated such that the claimed material is free of harmful particulate matter and gels having a diameter greater than 0.5 μm.

Applicant respectfully submits that the present amendments completely obviate the asserted basis for Examiner Dixon's position.

The present amendments are not intended to correct any error that was not identified in the original reissue declaration. Consequently, no new declaration is required under M.P.E.P. 1414.01. In view of the foregoing, applicant respectfully submits that all claims are now in condition for allowance and request the Examiner's favorable consideration thereof.

The present amendments are made without prejudice, and should in no way be deemed a concession regarding the alleged criticality of the "0.5 μm" limitation. Applicant expressly reserves its right to file a continuation application directed to claims maintaining the full breadth of claims 1-30 of the originally filed reissue application.

If the Examiner believes any issues remain with respect to the claims as presently amended, applicant respectfully requests that she call the undersigned to see whether those issues may not be summarily resolved.

Respectfully submitted,

Date: 1/24/03

By: _____
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Please amend claims 1 to read as follows:

1. (Amended) An improved composition for physiological applications, said composition containing hydroxypropylmethylcellulose in a physiological salt solution, the improvement comprising a hydroxypropylmethylcellose solution free of harmful particulate matter and gels greater than 0.5 μm in diameter, said viscoelastic solution having a zero shear viscosity in excess of 15,000 cps, an average molecular weight in excess of 250,000 Daltons and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human body.

Please amend claim 13 to read as follows:

13. (Thrice amended) A process for preparing a viscoelastic solution of hydroxypropylmethylcellulose in a physiological salt solution, the composition having a zero shear viscosity in excess of 15,000 cps and being free of harmful particulate material and gels greater than 0.5 μm in diameter and being pyrogen free and non-toxic when a therapeutically effective amount of said solution is injected into a human eye, the process comprising the steps of:

a) dispersing the hydroxypropylmethylcellulose in the salt solution to form a suspension,

b) heating the suspension of step (a) to about 95°C., allowing any undissolved material to settle and discarding the supernatant liquid above the undissolved material,

c) resuspending the undissolved material to form a second suspension of hydroxypropylmethylcellulose and heating the second suspension to form a thick gel,

d) filtering the gel through a series of filters to form a clean solution,

e) autoclaving the clean solution,

f) cooling the autoclaved clean solution and filtering the cooled solution, and

g) degassing the filtered cooled solution.

Please amend claim 25 to read as follows:

25. (Amended) A viscoelastic composition for injection into a human eye, the viscoelastic composition comprising hydroxypropylmethylcellulose in a physiological salt solution,

the hydroxypropylmethylcellulose having an average molecular weight greater than about 375,000 but less than about 420,000 and being present in a concentration from about 2.0% to about 2.5%,

the composition having a viscosity from about 25,000 centipoise to about 40,000 centipoise being free of harmful particulate matter and gels greater than 0.5 μm in diameter and being pyrogen free and nontoxic.

Please amend claim 27 to read as follows:

27. (Twice Amended) A process of preparing a sterile solution of hydroxypropylmethylcellulose in an aqueous solution, the sterile solution having a zero shear viscosity in excess of 15,000 cps and being non-toxic, non-pyrogenic, and substantially free of particulate matter and gels greater than 0.5 μm in diameter and harmful to the human eye, the process comprising the steps of:

a) dispersing hydropropylmethylcellulose in a first part of the aqueous solution to form a suspension;

b) allowing the suspension to settle to yield a supernatant and a sediment comprising high molecular weight hydroxypropylmethylcellulose;

c) discarding the supernatant, and leaving the sediment;

d) resuspending the sediment in a second part of the aqueous solution to form a gel;

e) filtering the gel through a plurality of successively finer filters to remove harmful particulate and gelatinous matter to form a clean solution; and

f) sterilizing the clean solution.